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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/619,924	07/15/2003	Gopi Venkatesh	451194-095	7145

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EXAMINER	
TRAN, SUSAN T	

ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
05/25/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 10/619,924	**Applicant(s)** VENKATESH ET AL.	
	Examiner Susan T. Tran	**Art Unit** 1615	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 14 May 2007 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☐ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires *3* months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☒ Applicant's reply has overcome the following rejection(s): 112, 1st paragraph.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *1-29*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: see detailed office action.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

SUSAN TRAN
PRIMARY EXAMINER

Art Unit: 1615

DETAILED ACTION

Response to Arguments

Applicant's arguments filed 05/14/07 have been fully considered but they are not persuasive.

Applicant argues that Gantt could not include a disintegrant since its addition would result in poorly friable tablets that fail to sustain the drug release. In contrast, Applicants could include a disintegrant in the tablet formulation to achieve tablet dispersion/disintegration within a minute because Applicants surprisingly discovered that the compressible coating of potassium chloride microcapsules would permit the addition era disintegrant to achieve rapid disintegration/dispersion into granules while maintaining controlled release characteristics.

Contrary to the applicant's argument, Gantt discloses the use of disintegrant including a wide variety of disintegrants suitable for compressed tablet (page 4, last paragraph bridging to page 5, first paragraph). Further, applicant's attention is called to page 5, lines 15-16, Gantt discloses the obtained tablet is strong and having low friability. Accordingly, Gantt clearly suggest including disintegrant to obtain a compressed tablet that is strong with low friability.

Applicant argues that Sheth discloses the use of a mixture of talc and magnesium stearate as a lubricant. Sheth further teaches the use of colloidal silicon dioxide as a lubricant. Presuming that Sheth believed that silicon dioxide are equivalent in their function as a lubricant, why would one use only the mixture of talc and magnesium stearate and not a mixture of colloidal silicon dioxide and talc or magnesium

stearate. Sheth failed to demonstrate rapid disintegration/dispersion into granules on contact with water and/or drug release profiles similar to that of the tablets prepared in accordance with the present.

However, in response to applicant's argument that Sheth failed to demonstrate rapid disintegration/dispersion into granules on contact with water and/or drug release profiles similar to that of the tablets prepared in accordance with the present, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). Sheth is relied upon solely for the teaching of silicon dioxide as a lubricant.

Applicant argues that nowhere does Remington list silicon dioxide to be used as a lubricant. In fact, Remington defines a glidant and states that colloidal silicon dioxide (Cab-O-Sil) is the most commonly used glidant.

However, in response to applicant's argument, Remington is not cited for the term "glidant" or "lubricant". Remington is cited for the teaching of using silicon dioxide as an excipient for compressed tablet is well known in the art. Gantt teaches the desirability of adding well-known excipient in pharmaceutical art suitable for compressed tablet.

Applicant argues that Gantt et al. and/or Oshlack et al. do not disclose or suggest the use of diethyl phthalate or another plasticizer for imparting compressible coating on

microcapsules which when incorporated into the tablet together with a disintegrant and colloidal silicon dioxide would result in tablets that rapidly disperse/disintegrate on contact with water.

However, in response to applicant's argument, Oshlack is relied upon solely for the teaching of the claimed plasticizer.

SUSAN TRAN
PRIMARY EXAMINER